

REMARKS

The present Amendment is in response to the Official Action mailed May 12, 2006. Claims 1-20 have been rejected in the present action. Claims 1-20 have been argued to overcome the Examiner's rejections. Claim 21 has been added. Therefore, claims 1-21 are currently pending in the present application. Applicants set forth remarks relating to the Official Action below.

As an initial matter, the Examiner has objected to the disclosure in the specification because it fails to indicate the relationship between the applications. In response to this, Applicants have amended the first paragraph of the present application to thereby correctly claim priority to prior applications. No new matter has been added to the application as a result of this amendment.

CLAIM REJECTIONS - 35 U.S.C. § 102(b) - Keller

In the present Action, the Examiner has rejected claims 1, 13-15, and 18-20 under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,997,432 to Keller ("the '432 patent"). The '432 patent is directed to a surgical instrument set having an implant and an inserter. The implant consists of two stop plates 3 and a sliding core 4. As shown in the figures of the '432 patent, the two stop plates are circular, and the intervertebral inserter (i.e. spreading forceps 9) includes two curved prongs (i.e. two spreading jaws 10, 11) that mate with the stop or base plates of the implant.

Independent claim 1 of the present application includes recitations directed towards a manipulation tool having an angled distal end. The angled distal end of the manipulation tool corresponds to the angled perimeter of at least one of the

base plates such that the movement of the base plate with the angled perimeter is limited by interference between the angled perimeter of the baseplate and the corresponding angled distal end of the manipulation tool. The angled distal end of the manipulation tool refers to the angled flat surfaces 420A, 420B, and 420C disposed on the end of the manipulation tool. These angled flat surfaces are discussed throughout the specification as for instance in paragraph [0087] of the present application. In addition, a lengthy discussion regarding these angled flat surfaces is included in paragraph [0140].

The Examiner asserts that the '432 patent discloses a spinal device with first and second baseplates 3 that are articulatable relative to one another and include angled perimeters the slope downward into the plate surface. Here, the Examiner is referring to the slope of the baseplates relative to one another. This is clearly different than what is included within claim 1 of the present application wherein the angled perimeter of the baseplates refer to the side surfaces of the baseplates being angled to one another as for instance walls 120A, 120B, and 120C.

The Examiner also asserts that the manipulation tool in the '432 patent has an angled distal end with jaws being angled to correspond to the angled perimeter ends of the baseplates. Once again, the Examiner is referring to the articulation of the baseplates and jaws relative to one another as opposed to the angled distal end which includes angled walls defining the distal end. The claims of the present application must be read in light of the specification which clearly asserts that the angled perimeter and angled distal end of the manipulation tool is with regard to the angled surfaces disposed at the various perimeter and distal ends. Once this clarification is taken into account, it is clear that the '432

patent only discloses a baseplate having a curved perimeter as well as a manipulation tool that only has jaws that include curved walls.

As shown in FIG. 4 of the '432 patent, the circular baseplate fits within the curved walls of the manipulation tool. This is contrasted to the present invention wherein the angled perimeter of the baseplates corresponds to the angled distal end of the manipulation tool.

Further, the Examiner notes in the present Action that the intended use as set forth in dependent claims 13, 14, 15, 19, and 20 carries no weight in the absence of any distinguishing structure, such that the device is capable of being used in any of the claimed surgical procedures. To this extent, the Applicants have set forth reasons showing the distinguishing structure of the baseplates and the manipulation tool in claim 1 of the present application in relation to the structure of the two stop plates 4 and the spreading forceps 9 as disclosed in the '432 patent.

Applicants contend that for the reasons set forth, Applicants have overcome the Examiner's rejection of claims 1, 13-15, and 18-20. The '432 patent does not disclose all of the limitations included within these claims. Thus, Applicants assert that claim 1 as well as dependent claims 13-15, and 18-20 are in condition for allowance and should be deemed patentable.

CLAIM REJECTIONS - 35 U.S.C. § 103(a) - Keller in view of McGahan

The Examiner has rejected claims 2-12, 16, and 17 under 35 U.S.C. 103(a) as being unpatentable over the '432 patent in view of PCT application WO 01/62191 to McGahan ("the '191 reference"). The Examiner acknowledges that the '432 patent fails to disclose the baseplates having three flat perimeter surfaces with two of the perimeter surfaces forming

corners. However, the Examiner contends that the '191 reference does teach such a structure and further contends that it would have been obvious to combine the two references to render claims 2-12, 16, and 17 unpatentable.

Claims 2-12, 16 and 17 depend from claim 1 of the present application and thus include all of the recitations of claim 1. As mentioned above, not only does claim 1 of the present application include a recitation directed towards the angled perimeters of the baseplate as well as the angled distal end of the manipulation tool, but also that the baseplates of the respective orthopedic device are articulatable relative to one another. In contrast, the '191 reference does not disclose a device with an articulatable portion. Specifically, the '191 reference is directed towards a manipulation tool for inserting a bone graft. The bone graft is a non-moveable single element. At no point does the '191 reference discuss that the bone graft may include a first portion, which is articulatable to a second portion.

Further, the '432 patent discloses an implant for attaching to two baseplates of a single implant that are only rested upon one another. If one were to use the inserter of the '191 reference with the implant of the '432 patent, a portion of the implant of the '432 patent would simply fall off the inserter of the '191 reference as the implant is being placed between two vertebrae. Therefore, if one was to combine the '191 reference with the '432 patent and incorporate all of the teachings of the '191 reference, one would be left with a device which is not articulatable relative to itself. Thus, the '432 patent and the '191 reference are not combinable.

In addition, the Examiner has not shown any motivation for their combination, as required by the United States Patent and Trademark Office standards. The Examiner further contends

that it would have been obvious to one of ordinary skill in the art to utilize angled flat perimeter surfaces on the plates and tool as taught in the '191 reference and modify the spinal implant and tool set of the '432 patent such "that it provides the surgeon with more precise control of the spinal implant as the device is implanted." In contrast to the Examiner's contention, the '432 patent at col.5, ll.57-62 teaches:

"The holding instrument 23 has an essentially U-shaped holding element which consists of two legs 24, 25. The legs normally assume the rest position shown in Fig. 8, in which the legs 24, 25 embrace the sliding core 4 only relatively loosely." (emphasis added)

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. M.P.E.P. § 2142. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. *Id.* In fact, the "relatively loosely" disclosure as outlined above in the '432 reference teaches away from that of the teaching of the present invention. Specifically, [0087] of the specification teaches:

"With regard to the inserter/impactor 400, by contrast, preferably, when the artificial intervertebral disc 160 is held by the inserter/impactor 400, the flat surfaces 180a-c are *tightly held* against the angled flat surfaces 420a-c of the inserter/impactor 400..." (emphasis added)

Once again, the '191 reference is cited for teaching a base plate having three flat perimeter surfaces with two of the perimeter surfaces forming corners. The '191 reference further teaches a spinal implant device with angled perimeter surfaces that are designed to engage the angled surfaces of the implant.

However, the implant of the '191 reference is limited to a single structure that cannot articulate relative to another part of the implant, as included in the claims of the present application. Thus, the '191 reference is not confronted with the sort of problem which confronts the present invention. Specifically, that the two base plates may move relative to one another during insertion.

Further, the base plates and sliding core of the '432 patent are not attached to one another and could become dislodged if all of them were not held during insertion. By applying the inserter of the '191 reference with the implant of the '432 patent, the '191 reference inserter only contacts one of the base plates. The remaining base plate as well as the sliding core may become dislodged during insertion. Thus, Applicants assert that claims 2-12, 16, and 17 based on their dependency from claim 1 are in condition for allowance and patentably distinct from the combination of the '432 patent of the '191 reference.

Nonstatutory Obviousness-Type Double Patenting Rejection

The Examiner has provisionally rejected claims 1, 4-12, and 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 19, and 20 of copending Application No. 10/663,487. In response to this rejection, Applicants have filed a terminal disclaimer disclaiming any patent rights which may be granted in the present application after the date in which patents rights will expire with regard to parent Application No. 10/663,487. The Examiner notes in the present Action that a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome a provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. The parent Application No. 10/663487 from which the rejection is based is commonly owned with this present application.

Therefore, in light of all of the above, Applicants respectfully submit that claims 1-20 distinguish over the cited prior art. As such, Applicants respectfully request that such claims be moved into a condition of allowance.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

Additionally, claim 21 has been added in the present Application. Claim 21 is a dependent claim directed to the manipulation tool further including a spacer having an upper and lower surface (See for example, FIG. 73 reference numerals 4200g and 4200h). The spacer is positioned adjacent to the angled distal end of the manipulation tool such that when the correspondingly angled distal end of the manipulation tool is engaged with the angled perimeter of the first or second baseplate, the articulation between the first and second baseplates is limited by the spacer being positioned between the two baseplates. This is generally described in [0141] and as seen in FIGS. 78-82. It is believed that neither the '432 patent nor the '191 reference alone or in combination teach the recitations of claim 21. Applicants request favorable consideration of new claim 21.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' agent at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/663,493

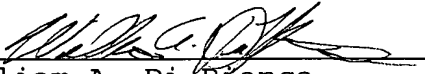
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If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 
William A. Di Bianca
Registration No.: 58,653
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

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